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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/575,878

09/15/2006

Siegfried Ansorge

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7055 7590 07/17/2009  
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EXAMINER

COPPINS, JANET L

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

07/17/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/575,878 | <b>Applicant(s)</b><br>ANSORGE ET AL. |  |
|                              | <b>Examiner</b><br>JANET L. COPPINS  | <b>Art Unit</b><br>1626               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 98-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 98-117 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Claims 98-117 are pending in the instant application.

***Priority***

2. The instant application is a 371 of PCT/EP2004/011644, filed October 15, 2004, which claims priority to DE Patent Application No. 103 48 044.7, filed October 15, 2003.

***Lack of Unity***

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention (which will be rejoined with the pending compound claims) to which the claims must be restricted:

Group I, claims 98 and 99, drawn to compositions comprising a compound of formula

C4, classified in various subclasses of classes 544, 546, 548, and 549. A further election of a single disclosed compound of formula C4 will be required if this Group is elected.

Group II, claims 100-103, drawn to methods of using compounds according to claims 98

and 99, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected.

Group III, claims 104-107 and 109-110, drawn to different methods of using compounds

according to claims 98 and 99, classified in various subclasses of class 514. A further election of a single disclosed compound of formula C4 as well as a single disclosed method will be required if this Group is elected.

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Group IV, claims 108 and 111, drawn to a stent, classified in various subclasses of class 514. A further election of a single disclosed compound of formula C4 will be required if this Group is elected.

Group V, claims 112-117, drawn to different methods of using compounds according to claims 98 and 99, classified in various subclasses of class 514. A further election of a single disclosed compound of formula C4 as well as a single disclosed method will be required if this Group is elected.

4. Where an election of one of Groups I-V is made, an election of a single disclosed compound (in the specification) is further required, including an exact definition of each substituent on the base molecule (Formula C4), wherein a **single member** at each substituent group or moiety is selected. For example, the base compound has the substituent group  $R^1$ , wherein  $R^1$  is recited to be any one of Hydrogen, alkyl, alkenyl, alkynyl, hydroxy, thiol, aryl or cycloalkyl, a heteroaromatic or heterocyclic residue, etc, and each subsequent variable position. In the instant case, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim that fall into the same class and subclass as the elected compound (or set of compounds). Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected species, as defined by the above Groups and common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the Lack of Unity requirement will not be made final until such

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time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compounds under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compounds are not patentable distinct, applicant should submit evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

5. Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B, **Part 1(c)**, further defines independent and dependent claims. Unity of

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invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, **Part 1(e)**, indicates the permissible combinations of different categories of claims. **Part 1(e(i))** states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)** indicates the "Markush practice" of alternatives in a single claim. **Part 1(f(i))** indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f(iv))** indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f(v))** indicates

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that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

6. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2, since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain an optionally substituted bicyclic (mono- or hetero-) ring system in common, which does not define a contribution over the prior art (**variables excluded**). Attached to the instant office action is a copy of a reference that provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a 'special technical feature' as defined in PCT Rule 13.2, by failing to define a contribution over the prior art, as it was known in the art prior to the filing of the instant application. Please refer to the CAPLUS abstract of Accession No. 2008:2172, to Dikumar et al, which teaches substituted benzimidazole compounds.

Further, under “Combinations of Different Categories of Claims {Annex B, Part 1(e)(I)}”, Applicants are permitted a process for examination on the merits whereas Applicants are claiming several different processes. For example, improving insulin resistance is not the same method as treating impaired glucose tolerance, or treating hyperlipidemia, since all three disorders involve different intracellular mechanisms and different treatment protocol. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571.272.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins  
Patent Examiner, Art Unit 1626  
July 13, 2009

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626



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